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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,428	08/06/2003	Balaji Venkataraman	52761-0100 (285976)	7339

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EXAMINER	
PESELEV, ELLI	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/635,428	VENKATARAMAN, BALAJI	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-27 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

VP

Claims 18-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 18-27 are directed to a method of treating or preventing a vascular disease or dementia. The only examples set forth in the specification are directed to the treatment of two patients for vascular disease. However, since the patients treated received other treatments such as (ACE) inhibitor and aspirin for patient 1 and a beta-blocker, diuretic and aspirin for patient 2, it is unclear if the improvement of vascular disease was achieved due to the claimed composition or other treatments received. Further, there is no evidence that the claimed methods are effective in preventing vascular disease and treating and preventing dementia. Note that the term "preventing" encompasses administering the claimed composition to healthy patients and preventing the same from ever getting vascular disease or dementia. The specification fails to provide any guidance on how to chose healthy subjects to whom the claimed composition should be administered and fails to teach whether the prevention is achieved for a period of days, months, years or whether permanent prevention is achieved.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Rowland (U.S. Patent No. 5,405,613), Paradissis et al (U.S. Patent No. 5,494,678) or Jackson (U.S. Patent No. 6,040,333.

Each of Rowland (column 14, lines 20-40), Paradissis et al (column 4, lines 6-55) and Jackson (column 2, lines 39-56) discloses the claimed composition comprising vitamin B12, vitamin B6, folic acid, magnesium and vitamin E and methods for administering said compositions. Note that Rowland also discloses said composition containing niacin (see, column 14, claim 2). The prevention of a vascular disease or dementia would have been inherent from such an administration.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowland (U.S. Patent No. 5,405,613), Paradissis et al (U.S. Patent No. 5,494,678) or Jackson (U.S. Patent No. 6,040,333) in combination with Horrobin et al (U.S. Patent No. 6,369,041.

Each of Rowland, Paradissis et al and Jackson et al discloses the claimed composition comprising vitamin B12, vitamin B6, folic acid, magnesium and Vitamin E

but do not disclose the use of a mixture of cyanocobalamin and hydroxocobalamin. However, since Horrobin et al disclose that cyanocobalamin and hydroxocobalamin are known forms of vitamin B12 (column 2, lines 19-20), a person having ordinary skill in the art at the time the instant invention was made would have been motivated to use a mixture of cyanocobalamin and hydroxocobalamin as vitamin B12 in compositions disclosed by Rowland, Paradissis et al or Jackson.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200

Elli Peselev